

EXHIBIT 52



Pharmacy

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Publix Opioid Task Force

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PLAINTIFF TRIAL
EXHIBIT
P-01375

Mission of Task Force

“To promote safe and efficient prescription processing of controlled substances by educating and equipping pharmacists with the tools and information needed to provide a premier patient experience”



Corresponding Duty

- 21 CFR 1306.04(a)
 - Pharmacists have a responsibility to avoid dispensing controlled substances that they know are not issued for a legitimate medical purpose
 - In order for a controlled substance prescription to be effective, it must be issued for a legitimate medical purpose by a prescriber in the usual course of his/her practice
 - However, a CORRESPONDING responsibility rests with the pharmacist filling the prescription
 - If pharmacist knowingly fills a prescription that is not legitimate, they shall be subject to penalties

Dealing with “Red Flags”

Red flags

Potential warnings signs that a controlled substance prescription is not being issued for a legitimate medical purpose

This can be known as diversion or abuse



- GOAL: to clear any red flags prior to filling a CS prescriptions and to document what red flags have been cleared
- Recommendations:
 - Provide continued guidance to pharmacists on identifying red flags
 - Attempt to clear red flags via communication with prescriber and/or patient
 - Pharmacist has a duty to clear all red flags prior to dispensing
 - Strongly encourage documentation of how red flags were cleared or how they were unable to be cleared, resulting in a refusal to fill

Role of Narcan in Opioid Dispensing



- Naloxone (Narcan) is an opioid antagonist that reverses the effects of opioids which can be lifesaving in the event of an opioid overdose
- Narcan should be offered to all at-risk patients, including but not limited to:
 - **50 MME/day or higher**
 - **Any patient on opioids with COPD or sleep apnea (regardless of MME)**
 - **Any patient on opioids AND benzodiazepine (regardless of MME)**
 - **Any patient receiving treatment for opioid use disorder including those on methadone, buprenorphine, or naltrexone**

Narcan Recommendations

- Remind and educate pharmacists that a Narcan standing order at Publix exists
 - allows pharmacist the ability to write for and dispense Narcan when warranted
 - Allows for both the patient and concerned family members of at-risk patients to obtain Narcan
- Strongly encourage or require Narcan counseling on all at-risk patients listed on previous slide
- Strongly encourage documentation that counseling took place or Narcan was refused by patient in “patient note”
- Creation of uniform handout for all “at-risk” patients
- Support for pharmacist to refuse dispensing of opioid if Narcan is refused in certain “at-risk” situations
- Consider a “compassionate care” program for waived copays on Narcan, if warranted
- Free Dispose-RX with initial fill/acute opioid prescriptions with education “Done with it? Dispose of it!”
- Soft PUB edit to identify excessive MME and recommendations to counsel patient accordingly

Understanding MME

- Morphine Milligram Equivalent (MME) is a metric used in gauging potency of a patient's opioid pain regimen.
- PDMP/E-Forsce helps pharmacists determine both individual drug MME and combined MME, as well as some smartphone apps:
- MME for individual prescriptions examples:
 - i.e. MME for Tramadol 50mg #90 = 15 MME
 - i.e. MME for Norco 10/325 #150 = 50 MME
- Combined MME for patients on multiple opioid examples:
 - i.e. MME for patient taking MS Contin 30mg #60 PLUS MSIR 15mg TID for breakthrough = 120 MME
 - i.e MME for Fentanyl 50mcg q3d PLUS Percocet 10/325 #120 = 180 MME
- MME Limits
 - 50MME/day is twice as likely to have accidental overdose compared to 20MME
 - 100MME/day is NINE times as likely to have accidental overdose compared to 20MME
 - Any opiate used in combination with benzodiazepines carries an even greater risk
 - According to NIH in 2019, 16% of accidental overdoses from opioids also involved benzodiazepines

Recommendations Regarding MME

- Understand that a high MME is not a reason, in and of itself, to not fill a CS prescription
 - Work needs to be done to clear red flags and educate patient on risks
- Strongly encourage pharmacist to check PDMP for control medications in all states, not just where it is mandatory (i.e. Florida)
- Learn how to appropriately interpret data on PDMP website
- Creation of checkbox or simple step in EnterpriseRx to replace typing “PDMP CHECKED, RX ACCEPTED” and if available through technology a space to put the MME on every single fill

Sample ALPDMP Look-up Information Candidate for Narcan Counseling

NARX SCORES

Narcotic

490

Sedative

400

Stimulant

000

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OVERDOSE RISK SCORE

330

(Range 000-999)

Summary

Total Prescriptions:45

Total Prescribers:4

Total Pharmacies:2

Narcotics* (excluding Buprenorphine)

Current Qty:0

Current MME/day:60.00

30 Day Avg MME/day:56.00

Sedatives*

Current Qty:0

Current LME/day:0.00

30 Day Avg LME/day:0.00

Buprenorphine*

Current Qty:0

Current mg/day:0.00

30 Day Avg mg/day:0.00

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Documentation of Highly Recommended Patient Notes

- If pharmacist **agrees** to fill at-risk medication combinations, high MME, and/or RX with Red Flags, it should be recommended that the pharmacist:
 - Document in patient notes and RX notes that the patient was counseled
 - Document how the Red Flags were cleared
 - Document that Narcan counseling took place
- If pharmacist **refuses** to fill these medications, documentation needs to be done stating what Red Flags exist and that they could not be cleared
 - Keep in mind, the DEA has previously stated the presence of ONE red flag that cannot be cleared is enough to refuse to fill a prescription
- Recommendations:
 - RDAC scan when PATIENT Note is deleted due to concern about the ease of the ability for any pharmacy associate to delete patients notes
 - Remind pharmacists that all patient notes should be typed professionally, be fact based, and be clear and concise

Handling “Opioid Naïve” Adjudication Rejections

- Often insurance will block RX for qty and limit to 7-day supply in opioid naïve patients
- Current practice exists in some pharmacies where the pharmacist is allowing patient to cash out or use discount card
- It is important that the pharmacist verify whether patient is truly opioid naïve
 - If **no**, consider calling insurance for one time override until MD can have opioid block removed
 - Provide MD and patient with information needed to have opioid block overridden (i.e. prior authorization)
 - If **yes**, the pharmacist assumes large risk to patient by overriding insurance block and going against the clear 3 day/7 day opioid guidelines for acute use
 - This practice should be discouraged and only allowed on a case-by-case basis with clear documentation of reason
 - Often 7 day supply is more than enough to provide patient with proper care until follow up with MD or prior auth can be obtained

GoodRx Usage Recommendations

- Recommend discouraging use of GoodRx(discount cards) for **all controlled substances**
 - Why? Direct-to-consumer advertising of pricing for controlled substances encourages polypharmacy which can directly increase NARX score and overdose risk score on PDMP
- GoodRx app/website clearly states in the FAQ section “This drug is a controlled substance. Note that some pharmacies may not honor coupons for controlled substances”



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Suggested *PUB Edits*

- **For Fentanyl**

- Fentanyl currently has a **black box warning** for use only in opioid tolerant patients
- EnterpriseRx should prompt pharmacist to enter PUB edit after they've confirmed the patient is not opioid naïve on any initial fill fentanyl patch prescription
- Patients are considered opioid tolerant after taking (FOR A WEEK OR LONGER):
 - 60mg/day of morphine for 7 days or more
 - Oral 30 mg/day of oxycodone for 7 days or more
 - Oral 8 mg/day of hydromorphone for 7 days or more
- Fentanyl is *contraindicated* in any patient:
 - Not opioid tolerant
 - Being treated for mgmt of acute or mild pain
 - Being treated for acute or post-operative pain
 - Being initiated in any dose exceeding 25 mcg/hr

Suggested *PUB Edits*

- For ARNP/PA Controlled Substance Prescribing
 - Pharmacists need to know how to check NPI taxonomy on NPI Lookup for prescribers
 - Important to know state specific prescribing laws for ARNPs and PAs in your state
 - For example:
 - Florida: only 7 days on ALL CII scripts
 - Florida: 30 days on CIII-CV
 - Florida: 30 days on stimulant CII *if* NPI shows the ARNP is a psychiatric nurse for adults/children
 - Alabama does not have this limitation for mid-level practitioners. We will need to verify with Legal if there are any other states that need this limitation edit
 - Can EnterpriseRx can use PUB EDIT based on DEA# starting with M (vs. A,B,F for physicians)

A retrospective audit would likely show pharmacists are allowing greater than 7 days as well as 30-day stimulant scripts because the system does

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Communicating with Patients and Providers

- Only **Pharmacists** should be communicating information with patients and/or prescribers
 - The pharmacists are making the clinical and professional decisions and therefore should not have technicians speak on their behalf or put them on the front lines for refusals to fill
 - When refusing to fill a controlled substance prescription, pharmacists struggle with how to approach the patient out of fear of confrontation
- Rule of thumb: **LESS IS MORE**
 - Do not use the words **RED FLAG** when speaking with patients and prescribers
 - Do not disparage the prescriber or make comments regarding their prescribing habits
 - Consider not using *generic refusals* such as “we don’t have this medication in stock”, “it’s on backorder”, or “we can’t order this medication”. Be honest.
 - If the patient has other passengers in their vehicle or a friend/family member with them, use caution regarding HIPAA. Consider asking the patient if it is ok to speak in front of their company

Communicating with Patients and Providers

EXAMPLES:

- Thank you for your patience today, I had the opportunity to evaluate the prescriptions you've dropped off (or that your prescriber sent over)
- Unfortunately, we've made a professional decision we can not fill these medications (or can no longer fill these medications, or this combination of medications)
- I understand it's frustrating, I'm sorry for any inconvenience this may cause you
- You'll need to find another pharmacy that can accommodate your needs
- You may need to work with your physician to address any concerns/issues

IF THE PATIENT CONTINUES TO ASK QUESTIONS OR APPEARS UPSET:

- Remain calm and remember less is more
- Repeat what you've already stated
- It is ok to acknowledge their frustration and apologize as you see fit
- It is ok to acknowledge that you must follow certain laws and guidelines and unfortunately based on that criteria, you have made a professional decision
- Use caution giving specific reasons and repeat the above as necessary
- REMAIN PROFESSIONAL AND CALM AT ALL TIMES
- BE COMPASSIONATE AND Caring
- Call front end management if you ever feel threatened or scared.

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Front End Management Support for Professional Decision Making

- Support from front end management is needed when decisions are made regarding refusals to fill
- Currently, an environment exists where patient complaints to front end management (seems against Publix Guarantee) can create strained relationships and present a divided front

Recommendations:

- CBT for customer service staff and front-end management to educate staff on importance of pharmacists' professional judgement in these situations

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Involved as responsible citizens in our communities.

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Proposed Procedural Checklist for Dealing with Fraudulent Controlled Substance Prescriptions

- Current Publix guidance below:
 - If fraud is caught prior to dispensing (FL specific)
 - After confirming with prescriber the Rx is fraudulent:
 - Report to your pharmacy supervisor, profile and deactivate RX (with rx notes)
 - Report to local non-emergency police department
 - Document case number
 - Report to Store Manager along with case #
 - Store Manager to do LP paperwork
 - If fraud caught after dispensing (FL specific)
 - All above steps must be taken, as well the following steps:
 - Report to DEA
 - Call Publix helpdesk and have RX removed from PDMP/EForsce
 - Reverse RX from any insurance or discount card
 - Profile RX, then inactivate RX, after placing patient and transaction notes re: fraud
- This information is not listed on Publix Connection and is not common knowledge to all pharmacists
- How to report prescribers of concern to the DEA Diversion website accessed through Publix Connection:
 - Publix Connection >> Reporting >> "Submit Tip to DEA" >> "RX ABUSE Online Reporting" >> "Complaint type" and select Suspicious Doctor/Practitioner >> Fill out form and submit

Take Home Points

- **Document. Document. Document.** If you don't document, then there is no proof the conversation, the consultation, or the clearing of red flags took place.
- When pharmacists are charged with the responsibility of making these clinical decisions, support from our Supervisors/Publix Leaders/Front End Management is essential



End Goal: The pharmacist dispensing the at-risk medications (or to the at-risk patient) should document the interaction so well that anyone coming behind them will not have any reason to question their decision. This would include other pharmacists, supervisors, DEA agents, or state inspectors.